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K001392

510(K) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: **Aaron 2100 High Frequency Electrosurgical Generator**
COMMON NAME: **Electrosurgical Generator**
CLASSIFICATION NAME: **Electrosurgical Cutting and Coagulation Devices and Accessories (21 CFR 878.4400)**

The **Aaron 2100 High Frequency Electrosurgical Generator** is a non-sterile, reusable multi-purpose electrosurgical generator for use in the operating arena which features both monopolar and bipolar functions which meet surgical demands for safety, flexibility, reliability, and convenience. Functions which the **Aaron 2100** performs includes: monopolar cut; monopolar cut with hemostasis (blend); force coagulation; fulguration; and bipolar.

The **Aaron 2100** is used to perform procedures such as laparoscopic tubal ligation, polypectomy, and small bowel or colon procedures.

SUBSTANTIAL EQUIVALENCE: The **Aaron 2100** is substantially equivalent to the Aaron 1200 Electrosurgical Generator (K980366) and the ValleyLab Electrosurgical Generator, Model SSE4 (K823924) in design, operation, intended use, materials, components, energy source, and performance claims.

TESTING: Testing which has been performed on the **Aaron 2100** indicates that this device and it's accessories are substantially equivalent in performance and method of operation.

HAZARD ANALYSIS: Hazard analysis evaluations were performed on the **Aaron 2100.** Test results indicated that there are no new hazards presented with the use of the **Aaron 2100 High Frequency Electrosurgical Generator** as compared with the predicate devices.

In conclusion, the **Aaron 2100 High Frequency Electrosurgical Generator** is substantially equivalent to the predicate devices in methods of operation, intended use, and results derived from operation.

Submitted By: Rick Kozloff
Vice President, Quality Assurance and Regulatory Affairs
Aaron Medical Industries, a Bovie Company
7100 40th Avenue North
St. Petersburg, FL 33710-2902
(727) 384-2323

Contact Person: Rick Kozloff
Date: April 27, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2000

Mr. Richard Kozloff
Vice President, Quality Assurance
and Regulatory Affairs
Aaron Medical Industries, Inc.
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K001382
Trade Name: Aaron 2100 High Frequency Electrosurgical Generator
Regulatory Class: II
Product Code: GEI
Dated: May 1, 2000
Received: May 2, 2000

Dear Mr. Kozloff:

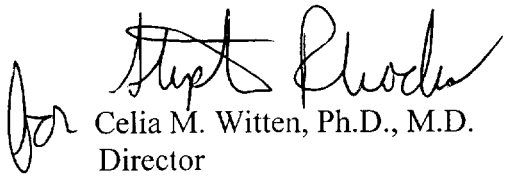
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K001382

Device Name: Aaron 2100 High Frequency Electrosurgical Generator

Indications For Use:

The **Aaron 2100 High Frequency Electrosurgical Generator** is a non-sterile reusable multi-purpose electrosurgical generator and accessories which is designed to perform monopolar and bipolar functions in the operating arena.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001382